

APPLICANT(S): LEVY, Andrew  
SERIAL NO.: 10/748,177  
FILED: December 31, 2003  
Page 5

#### REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

#### Status of the Claims

Claims 1-29 were pending in the Application. Claims 6-11, 20-25 and 29, which were withdrawn as pertaining to non-elected subject matter, have been cancelled. To expedite allowance of certain subject matter considered enabled by the Examiner, claims 2, 4, 5, 16, 18 and 19 have also been cancelled without prejudice or disclaimer, the subject matter of claims 5 and 19 incorporated into claims 3 and 17, respectively. As a result, claims 1, 3, 12-15, 17, and 26-28 are pending in the application. Applicants retain the right to pursue the subject matter cancelled herein in a future continuation application.

Applicants respectfully assert that the amendments to the claims add no new matter.

#### Remarks to the Cross Reference

In the Office Action, the Examiner indicated that the Cross-Reference needed to be updated.

An amended Cross Reference paragraph has been provided, now showing that US Patent Application No. 10/645,530, has been abandoned.

#### Information Disclosure Statement

The Examiner indicated that the listing of references in the application on pages 48-54 is not a proper information disclosure statement.

On March 14, 2006, an information disclosure statement including PTO 1449 and copies of all cited articles was submitted to this file. Applicant notes it was stamped received by the USPTO on March 24, 2006.

APPLICANT(S): LEVY, Andrew  
SERIAL NO.: 10/748,177  
FILED: December 31, 2003  
Page 6

**CLAIM REJECTIONS: 35 U.S.C. § 112**

In the Office Action, the Examiner rejected claims 1-5, 12-19 and 26-28 under 35 U.S.C. § 112, first paragraph. The Examiner contends that while the specification is enabling for a method for determining a potential of a diabetic patient to benefit from vitamin E therapy for treatment of CV death or MI wherein the benefit from said vitamin E therapy to a patient having a haptoglobin 2-2 phenotype is greater compared to patients having haptoglobin 1-2 phenotype or 1-1 phenotype, it does not reasonably provide enablement for any antioxidant therapy for treatment of any vascular complication.

With regard to vascular complication, by way of the foregoing amendments to independent claims 1 and 15, the vascular complications have been focused on cardiovascular complications, and vascular complications other than cardiovascular complications have been eliminated from the claims. The cardiovascular complication angina was added to claims 3 and 17, this subject matter supported by the specification on page 13, line 30. Applicant has addressed the Examiner's concern with regard to the complications in order to expedite allowance and retains the right to pursue the cancelled subject matter in the future. However, Applicant maintains that the specification is enabling for any anti-oxidant therapy.

As discussed in the specification, the Applicant discovered why inconsistent results emerged from numerous and sizeable clinical studies attempting to demonstrate benefit of antioxidant therapies in diabetic patients (c.g., those mentioned on page 6, lines 16-30). The Applicant identified the heretofore unrecognized variable, haptoglobin phenotype, and specifically patients with haptoglobin phenotype 2-2, as those benefiting from antioxidant therapy over the other phenotypes. The same principle applies to independent claim 15, wherein the importance of reducing oxidative stress is assessed. As pointed out in the specification (page 12, line 2, inter alia), haptoglobin 2-2 is an inferior antioxidant that predisposes diabetic patients to vascular complications (see Applicant's US 6,613,519). Thus, Applicant contends that the specification is enabling for correlating a greater importance of reducing oxidative stress or a greater potential benefit of antioxidant therapy for addressing cardiovascular complications in diabetic patients based on haptoglobin phenotype having a demonstrably poor antioxidant activity. Thus, the foregoing amendments

APPLICANT(S): LEVY, Andrew  
SERIAL NO.: 10/748,177  
FILED: December 31, 2003  
Page 7

render claims 1, 3, 12-15, 17, and 26-28 proper under 35 USC 112 first paragraph, and Applicant requests that the rejection be withdrawn.


### CONCLUSION

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,



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55,376

Dated: September 5, 2006

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APPLICANT(S): LEVY, Andrew  
SERIAL NO.: 10/748,177  
FILED: December 31, 2003  
Page 8

**Annotated Sheet Showing Changes to Specification**

The first paragraph of page 1 is amended as follows:

**CROSS-REFERENCE TO RELATED APPLICATIONS**

This is a continuation-in-part of U.S. patent application Ser. No. 10/645,530, filed Aug. 22, 2003, abandoned which is a continuation of U.S. patent application Ser. No. 09/815,016, filed Mar. 23, 2001, now U.S. Pat. No. 6,613,519, issued Sep. 2, 2003, which is a continuation-in-part of U.S. patent application Ser. No. 09/556,469, filed Apr. 20, 2000, now U.S. Pat. No. 6,251,608, issued Jun. 26, 2001, and which also claims the benefit of priority from U.S. Provisional Patent Application No. 60/273,538, filed Mar. 7, 2001. This Application also claims the benefit of priority from U.S. Provisional Patent Application No. 60/437,439, filed Jan. 2, 2003. The contents of all of the above listed applications are ~~[[is]]~~ hereby incorporated in full by reference.